IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA
Civil Action No: 1:15-CV-274

SYNGENTA CROP PROTECTION, LLC, Plaintiff, v. WILLOWOOD, LLC, WILLOWOOD USA, LLC, WILLOWOOD AZOXYSTROBIN, LLC, and WILLOWOOD LIMITED, Defendants.	)	DEFENDANTS' PRE-TRIAL BRIEF

Alan W. Duncan
N.C. State Bar No. 8736
L. Cooper Harrell
N.C. State Bar No. 27875
MULLINS DUNCAN HARRELL & RUSSELL PLLC
300 N. Greene Street, Suite 2000
Greensboro, NC 27401
Telephone: (336) 645-3320
Facsimile: (336)645-3330
aduncan@mullinsduncan.com
charrell@mullinsduncan.com

Of Counsel:
Peter J. Davis
WHITEFORD TAYLOR PRESTON LLP
Seven Saint Paul Street, Suite 1300
Baltimore, Maryland 21202-1626
Telephone: (410) 347-9425
Facsimile: (410) 223-4325
pdavis@wtplaw.com

Barry S. Neuman
WHITEFORD TAYLOR PRESTON LLP
1800 M Street, NW Suite 450N
Washington, DC 20036
Telephone: (202) 659-6761
Facsimile: (202) 327-6151
bneuman@wtplaw.com

Steven E. Tiller
WHITEFORD TAYLOR PRESTON LLP
Seven Saint Paul Street, Suite 1300
Baltimore, Maryland 21202-1626
Telephone: (410) 347-9425
Facsimile: (410) 223-4325
stiller@wtplaw.com

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases **Page**

Other Statutes

Defendants, Willowood, LLC, Willowood USA, LLC, Willowood Azoxystrobin, LLC, and Willowood Limited (collectively "Willowood" or "Defendants"), pursuant to the Court's Trial Scheduling Order, (Dkt. 136), respectfully submit this Pre-Trial Brief.

I. INTRODUCTION

This case arises out of the alleged infringement of four patents owned by Syngenta Crop Protection LLC ("Syngenta") claiming azoxystrobin and two particular methods to manufacture it. Azoxystrobin is a chemical compound included in certain fungicide products applied on various crops, including wheat, corn, and soybeans, to prevent and treat particular fungal diseases. Syngenta alleges that Willowood infringed each of these patents through its importation of azoxystrobin into the United States from China and subsequent sale of products including azoxystrobin.

While Defendants (other than Willowood Limited) concede that they infringed Syngenta's patents claiming the compound itself by importing into the United States five kilograms of azoxystrobin for the limited purpose of conducting certain testing and perfecting a method to formulate Willowood's ultimate end use products, Defendants dispute that such actions caused Syngenta any significant damages as they did not sell any azoxystrobin containing products prior to expiration of these patents. Defendants further dispute that they infringed either of Syngenta's patents claiming certain methods of manufacturing azoxystrobin. Finally, Defendants contend that one of these patents – covering a method of manufacturing azoxystrobin using a catalyst known as DABCO – is

invalid, as the use of DABCO to manufacture azoxystrobin was well known in the prior art before Syngenta filed for this particular patent.

II. PROCEDURAL HISTORY

Syngenta's original Complaint included seven causes of action – one asserting infringement of each of the four asserted patents, two asserting copyright infringement for Willowood's alleged copying of labels associated with two of Syngenta's azoxystrobin containing products, and a seventh asserting violation of North Carolina's Unfair and Deceptive Trade Practices Act stemming from Willowood's application to the EPA for approval of its azoxystrobin products under the EPA's formulator's exemption regulations. On August 12, 2016, this Court granted Willowood's motion to dismiss the unfair and deceptive trade practices claim on the grounds that it "is impliedly pre-empted by FIFRA." (Dkt. 74). Then, on April 10, 2017, this Court dismissed both of Syngenta's copyright claims, finding that Congress, in enacting the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA"), which regulates agrichemicals such as azoxystrobin, "intended a narrow exception to copyright protection for the required elements of [certain] pesticide labels…." (Dkt. 150). Additionally, the Court entered summary judgment against Willowood on infringement of the two patents covering the azoxystrobin compound itself with regard to the 5 kg of azoxystrobin imported prior to expiration of those patents for testing and formulation purposes given Willowood's concession on that issue. (Dkt. 141).

III. FACTUAL BACKGROUND

A. The Parties

Syngenta is the United States subsidiary of a global business that produces and sells agrichemicals and seeds. In 2016, Syngenta's parent was the world's largest crop chemical producer with approximately $12 Billion in sales, while Syngenta itself was one of the largest producers and distributors of those same products in the United States. Syngenta's products include nearly twenty active ingredients used by farmers as fungicides, as well as a host of other active ingredients sold as insecticides, herbicides and other agrichemicals. Syngenta also sells chemical products to the lawn and garden market.

Willowood develops, formulates and markets crop protection products for the United States agricultural industry. Willowood is a generic distributor of these products, meaning that Willowood develops and sells its products when any related patents expire consistent with regulations promulgated by the United States Environmental Protection Agency ("EPA"). Competition from Willowood, as well as other generic developers and distributors of crop protection products, often leads to lower prices for farmers, thereby reducing the cost of food to the consumer.

B. The Asserted Patents

Two of the patents asserted by Syngenta in this case – U.S. Pat. Nos. 5,602,076 and 5,633,256 (together, the "Compound Patents") – claim, among other things, the azoxystrobin compound itself. Both Compound Patents expired in February 2014.

A third asserted patent – U.S. Pat. No. 5,847,138 ("the '138 patent") – claims a particular method of manufacturing azoxystrobin. In this regard, the '138 patent claims a method of manufacturing azoxystrobin comprising two steps – an etherification step followed by a condensation step.

Finally, the fourth asserted patent – U.S. Pat. No. 8,124,761 ("the '761 patent") – claims the very same condensation step claimed by the '138 patent, except that the '761 patent requires that condensation be done "in the presence of between 0.1 and 2 mol %" of a common catalyst known as DABCO.

C. Infringement Allegations and Defenses

i. The Compound Patents

Very early in this litigation, certain of the Willowood defendants[1] conceded their infringement of the Compound Patents through the importation of a small amount of azoxystrobin – 5 kg – into the United States for the limited purpose of conducting certain testing required by the EPA and developing methods to formulate Willowood's ultimate end use products.[2] There is no dispute, however, that Willowood did not sell any

[1] Willowood Limited, based in Hong Kong, does not engage in any activities in the United States and thus may not be held liable for infringement of any United States patent. Willowood Limited's sole involvement in this case is that it originally acquires azoxystrobin from a supplier in China and then sells it to the other Willowood entities "F.O.B. China." As Willowood Limited passes title to the purchasing Willowood entity in China, it cannot be said to engage in any activities in the United States.

[2] Straight azoxystrobin (or "azoxystrobin technical" as it is commonly known) is typically not sold to growers for use on crops. Rather, azoxystrobin technical is mixed with other active and/or inert ingredients to form the end use products used by growers. Willowood provided some of the 5 kg of azoxystrobin imported by it to an independent

azoxystrobin-containing products in the United States, or import any azoxystrobin into the United States for sale, until several months after expiration of the Compound Patents.

There is no dispute that these testing and formulation services could have been performed outside the United States, thus avoiding any infringement allegations. In this regard, performing these testing and formulation services outside the United States would not have impacted Willowood's ability to receive EPA approval of its application to sell azoxystrobin. There are no regulatory or practical prohibitions to testing active ingredients or formulating end use products outside of the United States.

ii. The '138 Patent

Because the azoxystrobin sold by Willowood in the United States is manufactured in China, Syngenta's sole avenue of recourse against Willowood for infringement of both the '138 and '761 patents arises under 35 U.S.C. § 271(g) which provides, in pertinent part:

> Whoever, without authority, imports into the United States or offers to sell, sells or uses within the United States a product which is made by a process patented in the United States shall be liable as an infringer, if the importation, offer to sell, sale or use of the product occurs during the term of such process patent.

The Court has already concluded, (Dkt. 141), that the "single entity" rule requiring all steps of a claimed method to be performed by, or be attributable to, a single entity applies

---

formulator in the United States for the purpose of developing the formulations for its end use products.

to § 271(g).[3] Accordingly, for Willowood to be found liable under § 271(g), Syngenta must establish that both the etherification and condensation steps claimed in the '138 patent are performed in China by a single actor or, if more than one actor is involved, that the acts of one are attributable to the other, such that a single entity is effectively responsible for the infringement. (Dkt. 141 at 10).[4]

While Willowood conceded early in this litigation that the azoxystrobin it imports into, and sells throughout, the United States is manufactured using an etherification step followed by a condensation step, the preponderance of the evidence shows that two separate and independent companies performed these steps through a straight forward supplier/purchaser arrangement wherein one company simply purchased the intermediary compound from the other based on availability and price. In particular, documents produced by Willowood's Chinese supplier, Yancheng Tai He Chemicals Co., Ltd. ("Tai He"), show that Tai He, which performs the condensation step through a partner company, purchases the intermediary compound resulting from the etherification step in an arm's-length transaction from a wholly independent company known as Lianyungang Guosheng Chemical Co., Ltd. ("Guosheng"). Tai He's president, Wu Xiaolong ("Mr.

[3] Prior to importing any azoxystrobin into the United States, Willowood consulted with a licensed and experienced patent attorney to obtain advice regarding the '138 patent. This attorney correctly advised Willowood of the applicability of the single entity rule to infringement claims based on § 271(g).

[4] This Court held that if more than one actor is involved in practicing the claimed steps, "the acts of one are attributable to the other such that a single entity is responsible for the infringement ... in two sets of circumstances: (1) where that entity directs or controls [the] other's performance, and (2) where the actors [have formed] a joint enterprise." *Id.*

Wu"), confirmed this transaction and Tai He's arm's-length relationship with Guosheng during his deposition which will be shown to the jury during the trial of this matter. In fact, Mr. Wu testified that the facility at which the condensation step is performed is not capable of performing the etherification step and that Tai He purchased the intermediary resulting from that step from Guosheng because of its favorable pricing and ability to meet Tai He's supply needs; not as part of some joint enterprise or under Tai He's control. Accordingly, Willowood believes the evidence shows that it did not infringe the '138 patent.

iii. The '761 Patent

As set forth above, each of the asserted claims of the '761 patent claims a process for the preparation of azoxystrobin requiring that the claimed condensation reaction be conducted in the presence of "between 0.1 and 2 mol %" DABCO. Before purchasing any azoxystrobin from Tai He, Willowood specifically asked whether the azoxystrobin it manufactures is catalyzed during the condensation step using DABCO. Willowood was assured it was not. Not leaving things to chance, Willowood retained a laboratory in Hong Kong to test the azoxystrobin technical sold to it by Tai He. This laboratory did not find the presence of any DABCO. During this litigation, Willowood commissioned another independent laboratory to test the azoxystrobin imported by it from Tai He. That laboratory also found that DABCO was not present. Further, Mr. Wu, the only witness with first-hand knowledge of the manufacturing process at issue, testified that DABCO is not used during the condensation step when azoxystrobin is manufactured by Tai He.

On the other hand, Syngenta's sole support for its allegations that Willowood infringes the '761 patent is the testimony of its expert, Dr. Joseph Fortunak. Dr. Fortunak relies on two alleged facts to support his opinion: (i) that certain testing performed by Syngenta, *not an independent laboratory*, indicates the presence of an *unknown*, and very small, amount of DABCO in Willowood's end use product, which includes azoxystrobin, among other ingredients; and (ii) his belief that if one were to use DABCO in the manufacturing process, "it's only logical to run it in a commercially reasonable manner," – *i.e.*, between 0.1 and 2.0 mol %.

Dr. Fortunak, however, repeatedly conceded during his deposition that it is impossible to quantify the amount of DABCO used in the manufacture of Willowood's azoxystrobin based on Syngenta's limited testing. Dr. Fortunak attempts to circumvent this analytical conundrum by arguing that if azoxystrobin is manufactured in the presence of DABCO outside the range claimed by the '761 patent, (i) yield will be adversely affected, (ii) cost may be increased; and (iii) toxicity may be increased, and therefore, Tai He must use an infringing process.

Dr. Fortunak conceded during his deposition, however, that he does not know the concentration of DABCO at which yields will decrease;[5] that cost is not significantly

[5] In addition, the '761 patent itself discloses testing establishing that the yields recovered when manufacturing azoxystrobin in the presence of DABCO outside the claimed range are equal, or nearly equal, to yields recovered when manufacturing azoxystrobin in the presence of DABCO within the claimed range. *See* '761 patent, 8:12-20 (indicating in Table 1 that processing azoxystrobin in the presence of 0.1 mol % DABCO (outside the claimed range) yields 93.4% azoxystrobin while processing in the presence of 0.2 mol % DABCO (inside the claimed range) yields 93.1% azoxystrobin. Similarly, the patent

increased by using DABCO at increased concentration ranges; and that he does not know the concentration at which toxicity might become a concern. Accordingly, Syngenta's entire support for asserting Willowood's alleged infringement of the '761 patent consists of (1) testing conducted not by an independent laboratory, but by Syngenta itself, and (2) the entirely speculative testimony of its expert, which is contradicted by objective and unbiased evidence.

The '761 patent also is invalid, as a certain United States Patent Application ("Weintritt") – which published nearly two years before Syngenta filed for its patent – discloses and claims a process for manufacturing azoxystrobin using the exact same condensation reaction claimed by the '761 patent in the presence of "from 2 to 40 mol %" DABCO. Willowood's expert will testify that since catalysts can sometimes increase health hazards and waste disposal costs, persons knowledgeable in organic chemistry are generally motivated to decrease the level of any catalyst used in a reaction to its lowest possible useful level.

In the case of DABCO as used in the reaction claimed by the '761 patent, there is nothing extraordinary or unique about the 2 mol % level disclosed in the Weintritt reference. In other words, there is nothing inherent in the disclosure of the Weintritt application that would lead a person of ordinary skill in organic chemistry to believe that

---

discloses that processing azoxystrobin in the presence of 2.0 mol % DABCO (outside of the claimed range) yields 97.5% azoxystrobin while processing in the presence of 1.0 mol % DABCO (inside the claimed range) yields 98.7% azoxystrobin. Indeed, Dr. Fortunak testified that it was his understanding that at 0.1 mol % DABCO (again, outside the claimed range), the catalytic effect of DABCO becomes "close to … optimal."

the use of 2 mol % DABCO was the minimum that could be effective to catalyze the claimed condensation reaction or that the use of less than 2 mol % would not have catalyzed this reaction in a similar manner. Thus, according to Willowood's expert, a person of ordinary skill in organic chemistry investigating this reaction would be motivated to examine lower DABCO levels to reduce costs and lessen potential health hazards and expect that such lower levels would be effective.[6] Here, there is no indication in the Weintritt reference that the lower level of DABCO disclosed therein (2.0 mol %) represents a floor where the catalytic effects below such concentration would be unexpected. Indeed, the '761 patent itself discloses that the catalytic effect of DABCO using a concentration claimed by Weintritt (2.0 mol %) is nearly identical to the catalytic effect claimed by the '761 patent (1.0 mol %) – 97.5% versus 98.7%. As such, all that is

[6] Even without Willowood's expert's opinion, there still exists a serious question about the validity of the '761 patent as a *prima facie* case of obviousness exists where a particular amount or range of a compound is disclosed in the prior art that does not overlap with, *but is close to*, the amount or range claimed by the patent at issue. *See, e.g.*, *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 783 (Fed. Cir. 1985) (holding as proper the rejection of a claim directed to an alloy "having 0.8 % nickel, 0.3% molybdenum, up to 0.1% iron, balance titanium" as obvious over references disclosing alloys of 0.75 nickel, 0.25% molybdenum, with the balance being titanium and 0.94% nickel, 0.31% molybdenum and the balance being titanium. "The proportions are so close that *prima facie* one skilled in the art would have expected them to have the same properties); *In re Aller*, 220 F.2d 454, 456 (CCPA 1955) (the claimed process, which was performed at a temperature between 40°C and 80°C in an acid concentration between 25% and 70%, was held to be *prima facie* obvious over a reference that disclosed a process performed at a temperature of 100°C in an acid concentration of 10%); *In re Lillianfeld*, 67 F.2d 920, 924 (CCPA 1933) (prior art disclosing an alkali cellulous containing minimal amounts of water in the 5% to 8% range rendered obvious claims claiming an alkali cellulous with varying higher ranges of water (*i.e.*, "not substantially less than 13%," "not substantially below 17%," and "between about 13% and 20%")).

claimed in the '761 patent is an obvious modification of Weintritt – the use of DABCO at concentrations below 2.0 mol %. As such, Willowood believes that the evidence shows that the invention claimed in the '761 patent was obvious at the time of its conception, and therefore, the '761 patent is invalid.

IV. DAMAGES

As a result of Willowood's alleged infringement, Syngenta's damages expert claims that Syngenta has incurred the following damages:

Patent	Damages
Compound Patents	$75,663,000.00
'138 Patent	$135,522,000.00
'761 Patent	$273,418,000.00[7]

Syngenta's damages theories do not, however, rely on common infringement models. For example, one common damages model in a patent infringement case is known as "lost profits on lost sales." Under this model, Syngenta's damages would equal the profits it lost as result of each sale of azoxystrobin containing products made by Willowood. Under another common damages model, known as "price erosion," Syngenta's damages would be calculated by analyzing any reduction in prices caused by

[7] On June 19, 2017, upon Willowood's motion, the Court excluded Syngenta's expert's opinions regarding damages relating to the '138 and '761 patents as speculative and unreliable. The Court, however, noted that Syngenta's expert may testify to his opinion that lost profits for infringement of the '138 and '761 patents are at least as great as the lost profits for infringement of the Compound Patents. (Dkt. 202).

Willowood's allegedly improper sales and applying those price reductions to Syngenta's actual sales.

Syngenta eschews these common damages models, instead relying on a novel "benchmark" approach wherein Syngenta's damages are estimated by comparing its actual sales to its budgeted sales. As a result, the volume of Willowood's sales of allegedly infringing product and its market presence are entirely irrelevant to the analysis. That is, under Syngenta's analysis, Syngenta would have suffered $300 Million in damages on account of Willowood's alleged infringement whether Willowood sold 50,000 or 500,000 gallons of infringing product and whether Willowood's sales constituted 2% or 20% of all azoxystrobin sales in the United States.

In calculating damages related to the Compound Patents, Syngenta's damages expert, Dr. Ben Wilner, starts with Syngenta's budget shortfalls for all azoxystrobin products in 2014 through 2017 and then, with little justification, adjusts those shortfalls based on the percentage by which Syngenta failed to meet its budgets for an entirely different product, mesotrione, for those same years. Among the several fatal flaws in this analysis, however, is that Dr. Wilner offers no support as to why the Syngenta budgets should be trusted to any extent given their historical inaccuracy.

In this regard, Syngenta's 2009 azoxystrobin budget (five years before Willowood even entered the market) overestimated both gross sales and profits by 39%. Syngenta's 2010 budget was even farther off target as it overestimated gross sales by 39% and profits by 50%. Syngenta's budgets remained wildly inaccurate in 2011 when it underestimated

gross sales and profits by 39%. Although its estimates of both sales and profits in 2012 were off by less than 7%, its budgets in 2013 (with overestimates of gross sales and profit by 13% and 17%, respectively) and 2014 (with overestimates of gross sales and profit by 24% and 26%, respectively) were, again, grossly inaccurate.

Syngenta's budgets for each individual azoxystrobin containing product are even less reliable, as its 2012 budgets for the eight azoxystrobin products it sold at that time range from overestimates of 42% to underestimates of 72%. Similarly in 2013, Syngenta's budgets for its ten azoxystrobin products range from underestimates of 47% to overestimates of 28%. Syngenta's budgets for the azoxystrobin products sold in 2014 and 2015 were no more accurate as they range from overestimates of 220% to underestimates of 165%.

Syngenta's non-azoxystrobin product budgets fare no better as its mesotrione budget projections for 2012 through 2015 range from overestimates of 100% to underestimates of over 5,000%. Yet, despite these inaccuracies, Dr. Wilner uses the 2014 through 2017 azoxystrobin budgets as an accurate starting point for his damages analysis. Then, with virtually no rationale, Dr. Wilner contends that Syngenta's damages equal the shortfalls realized by Syngenta when comparing its actual sales to its budgeted sales in any given year adjusted by the percentage which Syngenta failed to meet its budgets for mesotrione for those same years. Mesotrione, however, is an herbicide used to prevent and treat the proliferation of weeds whereas azoxystrobin is a fungicide used to prevent and treat fungal diseases. Thus, mesotrione and azoxystrobin, *as conceded by Dr.*

Wilner, are subject to entirely different market conditions; yet Dr.Wilner offers no analysis of those differing market conditions.

Syngenta is limited to those damages arising out of Willowood's alleged infringement of the Compound Patents, *i.e*., any damages associated with Willowood's importation of 5 kg of azoxystrobin for the limited purpose of performing certain EPA required testing and perfecting a method to formulate Willowood's ultimate end use products. Willowood could have, however, performed these tests and contracted for these formulation services outside of the United States; thus, avoiding the scope of Syngenta's patents. Syngenta suffered no more simply because these actions took place in the United States. Further, given that Willowood made no sales during the term of the Compound Patents and its market share during the subsequent two to three years was so minimal (less than 5%), Willowood believes that Syngenta's damages analysis is simply implausible.

V. CONCLUSION

For the reasons stated herein and as will be proven at trial, Defendants believe that they will not be found to have infringed the '138 or '761 patents and that the '761 patent is invalid. While certain of the Willowood defendants concede that they infringed the Compound Patents through their importation of 5 kg of azoxystrobin for the limited purpose of performing testing and formulation services, they believe that Syngenta's resulting damages are minimal given that they did not make any sales of azoxystrobin containing products prior to those patents expiring.

This the 10th day of July, 2017.

/s/ L. Cooper Harrell
Alan W. Duncan
N.C. State Bar No. 8736
L. Cooper Harrell
N.C. State Bar No. 27875
MULLINS DUNCAN HARRELL & RUSSELL PLLC
300 North Greene Street, Suite 2000
Greensboro, NC 27401
Telephone: 336-645-3320
Facsimile: 336-645-3330
aduncan@mullinsduncan.com
charrell@mullinsduncan.com

/s/ Barry S. Neuman
Barry S. Neuman
WHITEFORD TAYLOR PRESTON LLP
1800 M Street NW, Suite 450N
Washington, DC 20036
Telephone: 202.659.6761
Facsimile: 202.327.6151
bneuman@wtplaw.com

/s/ Steven E. Tiller
Steven E. Tiller
WHITEFORD TAYLOR PRESTON LLP
7 Saint Paul Street
Baltimore, MD 21202
Telephone: 410.347.8738
Facsimile: 410.223.4304
stiller@wtplaw.com

Counsel for Defendants

OF COUNSEL:

Peter J. Davis
WHITEFORD TAYLOR PRESTON LLP
7 Saint Paul Street
Baltimore, MD 21202
Telephone: 410.347.8738
Facsimile: 410.223.4304
pdavis@wtplaw.com

CERTIFICATE OF WORD COUNT

In compliance with Local Rule 7.3(d), this Pre-Trial Brief contains 3,764 words according to Microsoft Word's word count feature.

This the 10th day of July, 2017.

/s/ L. Cooper Harrell
L. Cooper Harrell

CERTIFICATE OF SERVICE

The undersigned hereby certifies that the foregoing document has been filed electronically with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to counsel of record in this action.

This the 10th day of July, 2017.

/s/ L. Cooper Harrell
L. Cooper Harrell